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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,790	10/19/2001	Todd J. Mortier	7528.0003-01	6743

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EXAMINER

WILLSE, DAVID H

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/981,790

Applicant(s)

MORTIER ET AL. *cn*

Examiner

Dave Willse

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-30 and 45-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-30 and 45-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 23-30, 58, 63, 65-68, 70-73, and 75-78 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kusuhara, US 5,360,444. The embodiments of Figures 1-5, for example, include elongate members 7 and anchoring assemblies 5. As seen from column 4, lines 60-62, at least a portion of an elongate member 7 extends within a heart chamber such as the left atrium. Attention is also directed to column 4, lines 50-57. Regarding claim 23 and others, because the device can be used with a mitral valve 2, the drawing together of the leaflets and the alteration of heart geometry inherently shifts the position of at least one papillary muscle. Regarding claim 29: column 2, lines 41-45.

Claims 19-22, 45-57, 59-62, 64, 69, 74, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kusuhara, US 5,360,444. Regarding claims 19-21, additionally suturing a flexible annuloplasty ring (column 2, line 5) to the valve annulus would have been obvious in order to prevent enlargement of the occluder (column 1, line 38) along those annulus portions not adjacent to the anchoring assemblies 5. Regarding claim 22 and others, at least a portion of the anchor assemblies 5 or 25 being anchored to a heart wall surrounding a heart chamber would

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have been immediately obvious, if not inherent, because the material properties of said anchor assemblies (column 4, lines 26-43) would have impelled the ordinary practitioner to implant the device in a manner as to avoid contact with the valve leaflets and thus to prevent interference with leaflet movement and to reduce the possibility of tissue trauma. Regarding claims 74 and 79, portions of the sutures inherently traverse the heart wall; alternatively, mechanical anchors and the like were well known in the art and would have been an obvious variant in order to simplify the surgical procedure.

The Applicant's remarks have been reviewed but are deemed to be moot in view of the new grounds of rejection, which were necessitated by the added language involving "in situ" (e.g., claim 18, line 5) and "at least during systole" (e.g., claim 45, line 2). Therefore:

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, who is available Monday through Thursday and whose telephone number is (703) 308-2903. The supervisor, Corrine McDermott, can be reached at (703) 308-2111. The receptionist's phone number is (703) 308-0858, and the main FAX numbers are (703) 305-3591, 3590.

dhw: D. Willse  
July 25, 2003



**DAVE WILLSE**  
**PRIMARY EXAMINER**  
**ART UNIT 3738**